National Cancer Institute

Standard Operating Procedures

SUBJECT: Establishing User Accounts for the Clinical Trial Data Management Systems under the caBIG™ Program	SOP No.: IT-001
	Version No.: 2.0
	Effective Date: 12/11/2006
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Standard Operating Procedure –

Establishing User Accounts for the Clinical Trial Data Management Systems under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Department Approval:

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Chief Operating Officer, NCICB

QA Approval:

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George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

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1. Purpose

This Standard Operating Procedure (SOP) describes the process for establishing user accounts for accessing the clinical trial data management systems used in support of conducting clinical trials under the caBIG™ Program. This includes requesting, approving, creating and maintaining user accounts for all clinical applications supported by NCICB. Adherence to this SOP protects the security, privacy and data integrity issues of information conducted under NCICB supported clinical applications.

2. Scope

This SOP will be followed to request and approve access to NCICB clinical applications, create user accounts including passwords, and provide ongoing maintenance of user accounts for: a) research sponsored by the National Cancer Institute (NCI) and covered under the oversight of the caBIG™ Program, and b) the sharing of data across intramural and extramural sites, the regulatory community and commercial industry.

3. Requirements

3.1 Conducting background and security checks of users requesting access to clinical applications are and remain the sole responsibility of the local cancer research site (intramural and/or extramural site).

3.2 Users must request access to the system through the use of a User Requisition Template.

3.3 NCICB Application Support will approve the user's access and determine the user's appropriate level of access or role in accessing the clinical application. Where appropriate, NCICB Applications Support will verify with the party responsible for authorizing the user's access. NCICB Application Support will provide the user with a user name and a password. The password is set to expire upon initial user log in and must be re-established following the password rules established in the document "Guidelines for Establishing and Maintaining Passwords".

3.4 This document also addresses password lifetime, reuse of passwords, and locking of account after specified number of failed attempts to log on.

3.5 Where appropriate, training on the application must be completed prior to being granted access.

3.6 It remains the sole responsibility of the cancer research site (intramural or extramural site) to inform NCICB Application Administration Support when a current user's access must be revoked, limited or modified because of security issues, transfer of personnel, change in employment role or responsibility, separation or employment, or study status change (i.e., study closure hence access no longer required).

3.7 All appropriate intramural and extramural sites will use this SOP for guidance relative to establishing user accounts to NCICB supported clinical applications.

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4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	International Conference on Harmonization; Good Clinical Practice Guidelines, E6, Section 1.55
4.2	N/A	21 CFR 312.60 General Responsibilities of Investigators
4.3	AD004	SOP for Information Security Compliance
4.4	AD005	SOP for Protecting Patient Privacy
4.5	N/A	Title 21 CFR Part 11

5. Roles & Responsibilities

Role	Responsibility
User	• Requests access to the clinical data management application through the use of User Requisition Template.
Applications Support	• Reviews and approves user account. • Creates the user account and log in password.
Authorizer for Account Access	• Determines access for users to specific studies, projects and programs within the clinical application. • Provides guidance to Application Support relative to user access.
Site Training Coordinator	• Addresses training requirements.

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6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Process Description for Establishing and Maintaining User Accounts	This document provides instructions for the establishment and maintenance of user accounts. It establishes procedures and responsibilities to ensure that all staff responsible for this process conduct activities related to this SOP in a consistent manner. The content of this procedure should be followed strictly; any departure from this procedure should be documented and brought to the attention of senior clinical staff at the site.
2) User Requisition Template	Template for requesting access to NCICB applications for all users. Contains critical information necessary to establish a user account.
3) Guidelines for Establishing and Maintaining Passwords	Outlines guidelines to use when setting up passwords, including password naming conventions, locking of account, and expiration of passwords.
4) Process Flow for Establishing User Accounts	This Process Flow outlines the individual steps that need to be completed to grant access to users.